

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application: Marina V. Backer, et al.
Serial No. :
Filed : HERewith
For : RECOMBINANT PROTEINS CONTAINING SHIGA-LIKE
TOXIN AND VASCULAR ENDOTHELIAL GROWTH
FACTOR FRAGMENTS

Examiner :
Attorney Docket : 102108-300
Group Art Unit :
Confirmation No. :
Customer No. : 27267

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the United States Postal Service, Express Mail, in an envelope
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for Patents, Alexandria, VA 22313-1450 on 27 JAN 2004.

By

Todd E. Garabedian
Todd E. Garabedian, Ph.D.
Registration No. 39,197
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* * * * *

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Assistant Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.56, the Examiner is respectfully
requested to consider the references cited on attached Form PTO-
1449. A copy of each reference (if not previously submitted) is
enclosed. It is respectfully requested that the information be
expressly considered during the prosecution of this application,
and that the reference(s) be made of record therein and appear
among the "References Cited" on any patent to issue therefrom.

- [X] 1. This Information Disclosure Statement is being filed
within three months of the U.S. filing date OR before the
mailing date of a first Office Action on the merits. No
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- [] 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- [] a. Each item of information contained on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1); and no fee is required under 37 C.F.R. §1.17(p).
- [] b. No item of information cited on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2); and no fee is required under 37 C.F.R. §1.17(p).
- [] Please charge Deposit Account No. 23-1665 in the amount of \$240.00 in payment of the fee under 37 C.F.R. §1.17(p). Two additional copies of this Information Disclosure Statement are enclosed.
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- [] b. No item of information cited on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).
- [] Please charge Deposit Account No. 23-1665 in the amount of \$130.00 in payment of the fee under 37 C.F.R. §1.17(i)(1). Two additional copies of this Information Disclosure Statement are enclosed.
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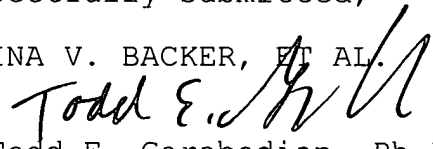
The undersigned represents that the closest art of which he is presently aware has been cited herein and understands that this statement shall not be construed as a representation that no better art exists or that a thorough patentability search has been made.

The undersigned further represents that the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

Respectfully submitted,

MARINA V. BACKER, ET AL.

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Date: 27 JAN 2004

PATENT

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By Todd E. Garabedian
Todd E. Garabedian, Ph.D.
Registration No. 39,197
Attorney for Applicant(s)

INFORMATION DISCLOSURE LETTER

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U. S. Patents

1. U. S. Patent No. 6,037,329, issued March 15, 2000 to Baird, et al.
2. U. S. Patent No. 6,036,955, issued March 14, 2001 to Thorpe, et al.

Other Documents

1. "Hypoxic Regulation of Vascular Endothelial Growth Factor in Retinal Cells", Aiello et al., *Arch/Ophthalmol.*, Vol. 113, pp. 1538-1544, 1995.
2. "Cytotoxicity of a Shiga Toxin A Subunit-CD4 Fusion Protein to Human Immunodeficiency Virus-Infected Cells, Al-Jaufy et al., *Infection and Immunity*, Vol. 62, No. 3, pp. 956-960, 1994
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Journal of Cellular Physiology, Vol. 149, pp. 50-59, 1991.

7. "Increased Expression of Vascular Permeability Factor (Vascular Endothelial Growth Factor) and Its Receptors in Kidney and Bladder Carcinomas", Brown et al., *American Journal of Pathology*, Vol. 143, No. 5, pp. 1255-1262, 1993.
8. "Expression of Vascular Permeability Factor (Vascular Endothelial Growth Factor) and Its Receptors in Breast Cancer", Brown et al., *Human Pathology*, Vol. 26, pp. 86-91, No. 1, 1995.
9. "Construction of Mutant Genes for a Non-Toxic Verotoxin 2 Variant (VT2vp1) of *Escherichia coli* and Characterization of Purified Mutant Toxins", Cao et al., *Microbiol. Immunol.*, **38**(6), pp. 441-447, 1994.
10. "Regulation of VEGF/VPF expression in tumor cells: Consequences for tumor growth and metastasis", Claffey et al., *Cancer and Metastasis Review*, **15**, pp. 165-176, 1996.
11. "Vascular Endothelial Growth Factor/Vascular Permeability Factor (VEGF/VPF) in Normal and Atherosclerotic Human Arteries", Couffinhal et al., *American Journal of Biology*, Vol. 150, No. 5, pp. 1673-1685, 1997.
12. "The role of tyrosine-114 in the enzymatic activity of the Shiga-like toxin 1 A-chain", Deresiewicz et al., *Mol. Gen. Genet*, Vol. 241, pp. 467-473, 1993.
13. "Overexpression of Vascular Permeability Factor/Vascular Endothelial Growth Factor and its Receptors in Psoriasis", Detmar et al., *J. Exp. Med.*, Vol. 180, pp. 1141-1146, 1994.
14. "Angiogenesis", Folkman et al., *The Journal of Biological Chemistry*, Vol. 267, No. 16, pp. 10931-10934, 1992.
15. "Angiogenesis in cancer, vascular, rheumatoid and other disease", Folkman, *Nature Medicine*, Vol. 1, pp. 27-31, 1995.

16. "Minimum Domain of the Shiga Toxin A Subunit Required for Enzymatic Activity", Haddad et al., *Journal of Bacteriology*, Vol. 175, No. 16, pp. 4970-4978, 1993.
17. "Signaling Vascular Morphogenesis and Maintenance", Hanahan, *Science*, Vol. 277(5322), pp. 48-50, 1997.
18. "Ribotoxic Stress Response: Activation of the Stress-Activated Protein Kinase NK1 by Inhibitors of the Peptidyl Transferase Reaction and by Sequence-Specific RNA Damage to the α -Sarcin/Ricin Loop in the 28S rRNA", Jordanov et al., *Molecular and Cellular Biology*, Vol. 17, No. 6, pp. 3373-3381, 1997.
19. "Recent advances in understanding the pathogenesis of the hemolytic uremic syndromes", Kaplan et al., *Pediatric Nephrology*, Vol. 4, pp. 276-283, 1990.
20. "Inhibition of vascular endothelial growth factor-induced angiogenesis suppresses tumour growth *in vivo*", Kim et al., *Nature*, Vol. 362, pp. 841-844, 1993.
21. "Glioblastoma growth inhibited *in vivo* by a dominant-negative Flk-1 mutant", Millauer et al., *Nature*, Vol. 367, pp. 576-579, 1994.
22. "Vascular Endothelial Growth Factor And Its Receptors", Neufeld et al., *Progress in Growth Factor Research*, Vol. 5, pp. 89-97, 1994.
23. "Vascular endothelial growth factor (VEGF) and its receptors", Neufeld et al., *The FASEB Journal*, Vol. 13, pp. 9-22, 1999.
24. "Targeting The Tumor Vasculature: Inhibition Of Tumor Growth By A Vascular Endothelial Growth Factor-Toxin Conjugate", Olson et al., *Int. J. Cancer*, Vol. 73, pp. 865-870, 1997.
25. "Endothelial Heterogeneity in Shiga Toxin Receptors and Responses", Obrig et al., *The Journal of Biological Chemistry*, Vol. 268, No. 21, pp. 15484-15488, 1993.
26. "Pathogenesis of Haemolytic Uraemic Syndrome", Obrig et al., *The Lancet*, p. 687, September 1987.

27. "Up-Regulation of Vascular Endothelial Growth Factor and Its Cognate Receptors in a Rat Glioma Model of Tumor Angiogenesis", Plate et al., *Cancer Research*, Vol. 53, pp. 5822-5827, 1993.
28. "Vascular Endothelial Growth Factor-Toxin Conjugate Specifically Inhibits *KDR/flk-1*-positive Endothelial Cell Proliferation *in Vitro* and Angiogenesis *in Vivo*", Ramakrishnan et al., *Cancer Research*, Vol. 56, pp. 1324-1330, 1996.
29. "The Histopathology of the Hemolytic Uremic Syndrome Associated with Verocytotoxin-Producing *Escherichia coli* infections", Richardson et al., *Human Pathology*, Vol. 19, No. 9, pp. 1103-1108, 1988.
30. "Inhibition of Growth of C6 Glioma Cells *in Vivo* by Expression of Antisense Vascular Endothelial Growth Factor Sequence", Saleh et al., *Cancer Research*, Vol. 56, pp. 393-401, 1996.
31. "Shiga Toxin, Shig-like Toxin II Variant, and Ricin Are All Single-site RNA N-Glycosidases of 28 S RNA When Microinjected into *Xenopus* Oocytes", Saxena et al., *The Journal of Biological Chemistry*, Vol. 264, No. 1, pp. 596-601, 1989.
32. "Biological properties of VEGF/VPF receptors", Terman et al., *Cancer and Metastasis Reviews*, Vol. 15, pp. 159-163, 1996.
33. "Renal dysfunction accounts for the dose limiting toxicity of DT₃₉₀ati-CD#sFv, a potential new recombinant anti-GVHD immunotoxin", Vallera et al., *Protein Engineering*, Vol. 10, No. 9, pp. 1071-1076, 1997.
34. "VEGFs, receptors and angiogenesis", Veikkola et al., *Cancer Biology*, Vol. 9, pp. 211-220, 1999.
35. "THE RNA-N-GLYCOSIDASE ACTIVITY OF SHIGA-LIKE TOXIN I: KINETIC PARAMETERS OF THE NATIVE AND ACTIVATED TOXIN", Brigotti et al., *Toxicom*, Vol. 35, No. 9, pp. 1431-1437, 1997.

36. M. V. Backer, et al., "Engineering S-protein fragments of bovine ribonuclease A for targeted drug delivery", *National Library of Medicine*, Vol. 26, No. 3, pp. 455-461, 2002.
37. M. V. Backer, et al., "Targeting endothelial cells overexpressing VEGFR-2: selective toxicity of Shiga-like toxin-VEGF fusion proteins", *National Library of Medicine*, Vol. 12, No. 6, pp. 1066-1073, 2001.
38. M. V. Backer, et al., "Shiga-like toxin-VEGF fusion proteins are selectively cytotoxic to endothelial cells overexpressing VEGFR-2," *National Library of Medicine*, Vol. 74, No. 1-3, pp. 349-355, 2001.

The undersigned represents that copies of art cited herein (the two U. S. Patents and items 1 through 35 above) have been previously submitted to the United States Patent and Trademark Office with Patent Application Serial No. 09/796,861. The undersigned further represents that copies of the art cited in items 36 through 38 above are enclosed herein.

If the Examiner has any questions or feels that a discussion with Applicants' representative would expedite prosecution, the Examiner is invited and encouraged to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

MARINA V. BACKER, ET AL.

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Date: 27 JAN 2004

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | ATTY. DOCKET NO. 102108-300 | | SERIAL NO. | | |
| | | APPLICANT: MARINA V. BACKER, ET AL. | | | | |
| | | FILING DATE: HEREWITH | | GROUP: | | |
| U.S. PATENT DOCUMENTS | | | | | | |
| EXAMINER INITIAL* | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROP. |
| | 6,037,329 | March 14, 2000 | Baird, et al. | 514 | 44 | Sept. 24, 1996 |
| | 6,036,955 | 3/14/01 | Thorpe et al. | 424 | 136.1 | June 7, 1995 |
| FOREIGN PATENT DOCUMENTS | | | | | | |
| | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION Yes No |
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| OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) | | | | | | |
| 1. | "Hypoxic Regulation of Vascular Endothelial Growth Factor in Retinal Cells", Aiello et al., <i>Arch/Ophthalmol.</i> , Vol. 113, pp. 1538-1544, 1995. | | | | | |
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